

# Cell and Gene Therapy Development and Clinical Manufacturing Center

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Senior Vice President, BioCentriq™



## BioCentriq™ is a Full Service Concept-to-Clinic CDMO

# **Process** Development Application Development Bio**Centriq** ™ Workforce Development Clinical Production

**Our Services** 

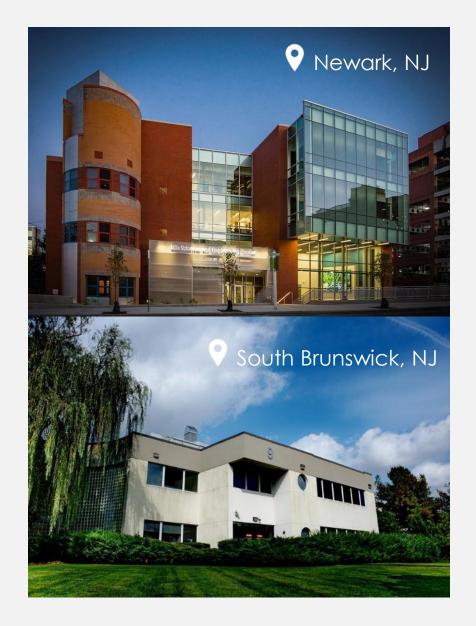
### **Our Advantage**



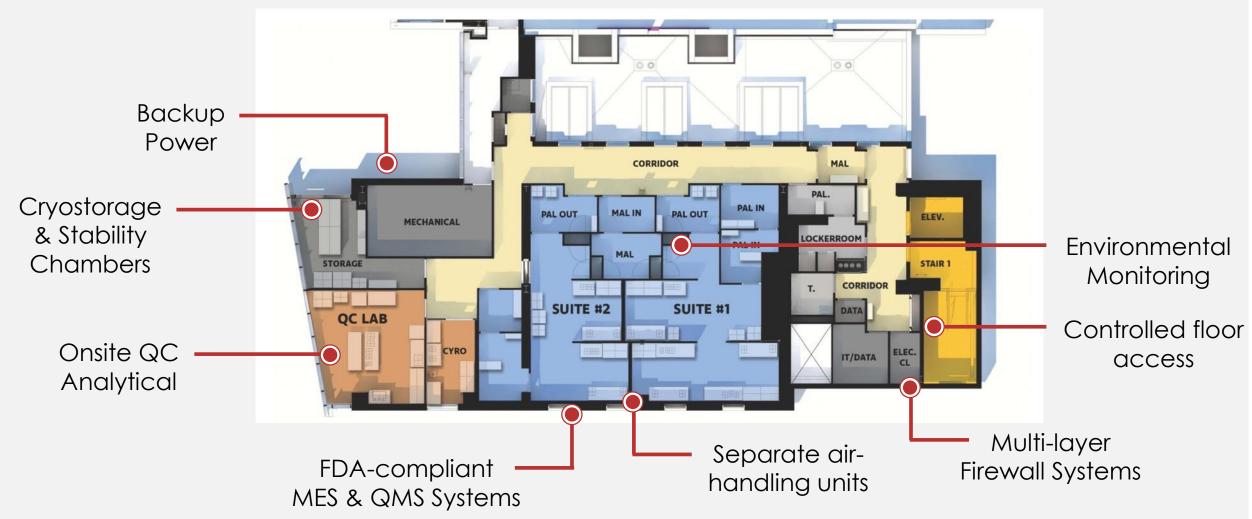
## Two State-of-the-art Facilities

BioCentriq has two multi-million dollar facilities located in Newark and South Brunswick:

- Newark: ISO-7 certified clinical manufacturing facility
- South Brunswick: BSL-2 certified process development facility
- Industry-leading processing and analytical equipment
- Full access, hybrid teams, and collaborative approach



# A Fully Validated GMP Facility & Quality Systems





## **GMP Clinical Production Facility**



**Cell Therapy** 

**Autologous** 

Allogeneic

Multiple Cell Types

**Analytical and Quality Services** 



**Gene Therapy** 

**Viral Vector Production** 

**Viral Banks** 

**Upstream Processing** 

**Downstream Processing** 



Immunotherapy & Vaccines

**Monoclonal Antibodies** 

**Proteins** 

**Vaccines** 

## **Fully Equipped Process Development Facility**



## **Process Development Center**



#### Capabilities

**Cell Therapy** 

**Viral Vector** 

Non-Viral

**Analytical Methods** 



#### **Services**

Full customer access

Hybrid teams

Tech transfer & process migration

Analytical method development

Downstream purification & testing



Capacity

Batch and continuous processing

## **Processing Technology Highlights**



CLINIMACS Prodigy



Pall iCELLis 500



Cytiva Flex Factory



Sartorius Ambr 15



Pall Allegro STR 200



Pall iCELLis Nano



Sartorius CM150 TFF



Pall Allegro XRS 25



Sartorius Cadence BioSMB

## **Adherent Cell Systems**

Scale-up & Clinical Production

#### **Process Development**

Screening, Media Design & Optimization



Corning/Thermo Flasks, Hyperflasks 5mL – 560mL



**PALL** iCELLis Nano 600mL – 4L



**PALL** iCELLis 500 72L – 500L

#### **Working Volume**

## **Suspension Cell Systems**

Scale-up & Clinical Production

**Process Development** 

Media Design & Optimization

#### Screening



Sartorius Ambr 15 10-15 mL



Corning/Thomson Shake Flasks 24mL – 3.2L



Sartorius BioStat B-DCU 1L – 10L



PALL Allegro XRS 25 2L – 25L



PALL STR 50, STR 200 10-50L, 60-200L

#### **Working Volume**

## **Analytical Capabilities Highlights**

Dose: Cell count & viability

**Identity:** Cell marker identification & gene expression

Potency Testing: Proliferation, cytotoxicity, ELISA, enzyme activity,

cell count & viability, viral vector titer

Purity Testing: Identification & residual host cell DNA

Compendial Methods: Endotoxin, sterility, and bioburden testing



NC-200 Cell Counter



ViCELL Blu Cell
Counter



Bio-Rad ddPCR



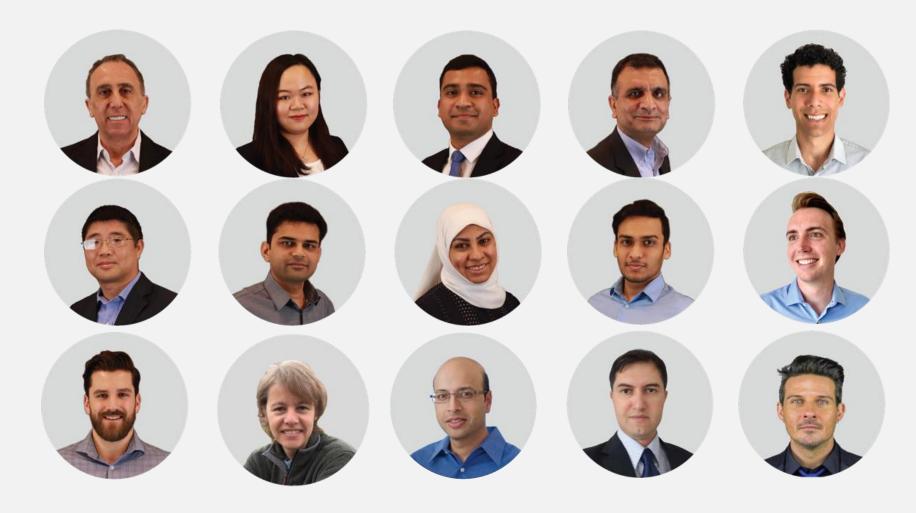
Nova Bioflex



Cytoflex Flow Cytometer

## **Experienced and Collaborative Team**

"Over a century of industry experience"



## Guided by Impressive Advisory Committee



Joanne Beck, Ph.D.
Boston Pharmaceuticals



Peter Marks, M.D., Ph.D.
FDA - CBER



Steve Dziennik, Ph.D.

Merck



Joseph Tarnowski, Ph.D.

GlaxoSmithKline



Hari Pujar, Ph.D. Flagship Pioneering



**Beth Webb** GE-Cytiva



**Greg Russotti, Ph.D.**Century Therapeutics



**Rick Morris, Ph.D.**Pall Biotech



David Pollard, Ph.D.
Sartorius



Mayo Pujols, M.Sc. Andelyn Biosciences



Kelvin Lee, Ph.D.



**Kevin Belfield, Ph.D.** *NJIT* 

## BioCentriq is Designed to Overcome Challenges







Available cGMP Facilities

Hybrid Team Model

**Experienced Scientists & Engineers** 



Strategic Sourcing of Materials



Rapid Project Initiation



Flexible Pricing Models

## Take a Virtual Tour!



## Contact Us For Your Next Project



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